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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,536	01/29/2001	William H.R. Langridge	12273-3	9620

7590

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/29/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/771,536

Applicant(s)

LANGRIDGE ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50- 86 is/are pending in the application.
- 4a) Of the above claim(s) 65- 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50- 64 and 69- 86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16, 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant confirmed the election of Group III without traverse and cancelled claims 1- 49. Applicant requested rejoinder of method (claims 65- 68) of using a patentable product or in the alternative authorizes the Office to cancel the claims if it determines the claims should not be maintained. The Office will hold the claims withdrawn at this time unless otherwise specifically directed by Applicant.

This action is on claims 50- 64 and 69- 86.

### ***Rejections Withdrawn***

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 50- 64 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 50- 64 were also rejected under 35 U.S.C. 112, second paragraph, as they are not clear in what is meant by fusion. In claims 53 and 55 it was not clear if "can" intends the inclusion of the second part of the claim.

Applicant amended the claims to clarify the meaning. Rejections withdrawn.

***Claim Rejections - 35 USC § 102***

Claims 50, 53, 54, and 63 were rejected under 35 U.S.C. 102(b) as being anticipated by Hajishengallis et al. (J. Immunology 1995 vol 154: 4322- 4332).

The amendments overcome the art rejection.

Claims 50, 53, 54, and 63 were rejected under 35 U.S.C. 102(e) as being anticipated by Russell (US 6030624).

The amendments overcome the art rejection.

***Rejections Maintained***

***Claim Rejections - 35 USC § 102***

Claims 50, 51, 58 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Gonzalez et al. (Gene 1993, 133: 227- 232).

Applicant's argument that the claim is amended to include the limitation of "where the antigen elicits a protective response to the disease" and that the product of Gonzalez did not protect.

Applicant's arguments have been fully considered and not found persuasive.

Gonzalez teaches the same structure as recited in the claims. Gonzalez discloses a protein complex comprising 5 monomeric fusion proteins where each fusion

protein comprises a Cholera toxin B subunit linked to a immunogenic antigen (rotavirus antigen) (Abstract, Figure 1 and Figure 3).

It would be expected that the same product administered by the same route would produce antibodies that meet the limitation of the claim as now written. The rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzalez as applied to claims 50, 51, 58 and 63 above, and further in view of Manson et al. (TIBTECH September 1995 vol. 13: 388- 392).

Applicant's argument that the claim is patentable now over the reasons given for the reasons above in the 102(b) rejection.

Applicant's arguments have been fully considered and not found persuasive.

As explained above, the rejection stands for reasons set out above in Gonzalez as applied to claims 50, 51, 58 and 63.

The rejection is maintained.

### ***New Rejections Based on Amendment***

### ***Claim Rejections - 35 USC § 112***

Claims 63 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. In clause beginning with "upon" in both claims, it is not clear that expression in plants is required and that that is a product by process limitation and adds no patentable weight to the claims unless the product made is different in some way.

***Claim Rejections - 35 USC § 103***

Claims 53- 57 and 59- 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzalez as applied to claims 50, 53, 54, and 63 above, and further in view of Hajishengallis.

Gonzalez discloses a protein complex as discussed above and of record in paper #12.

Gonzalez does not teach an additional cholera toxin (CT) subunit or additional antigens.

Hajishengallis discloses a CT fusion protein comprising the A2 subunit and an immunogenic antigen for a causal factor of a mammalian disease and that the A2 fusion forms a complex with CT B subunit (Figure 1, and paragraph spanning 4330- 4331).

One of ordinary skill in the art at the time of the invention would have motivated to combine cholera toxin subunit fusion proteins because they are known to form complexes and the that each subunit can be constructed with a different immunogenic antigen as taught by Gonzalez and Hajishengallis.

Thus it would have been *prima facie* obvious to combine the subunits of Gonzalez and Hajishengallis with the expectation of success.

Claims 64, and 69- 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzalez and Manson as applied to claim 52 above, and further in view of Hajishengallis.

Gonzalez discloses a protein complex as discussed above and of record in paper #12.

Gonzalez does not teach an additional cholera toxin (CT) subunit or additional antigens.

Manson teaches benefits of CT as an oral adjuvant and can be used to express heterologous antigens and also teaches that both subunits can be expressed in plants to gain the enhanced effect of the holotoxin (section starting page 389, second to last paragraph).

Hajishengallis discloses a CT fusion protein comprising the A2 subunit and an immunogenic antigen for a causal factor of a mammalian disease and that the A2 fusion forms a complex with CT B subunit (Figure 1, and paragraph spanning 4330- 4331).

One of ordinary skill in the art at the time of the invention would have been motivated to combine cholera toxin subunit fusion proteins because they are known to form complexes and the that each subunit can be constructed with a different immunogenic antigen as taught by Gonzalez and Hajishengallis and express them in plants.

Thus it would have been *prima facie* obvious to combine the subunits of Gonzalez and Hajishengallis in plants as taught by Manson with the expectation of success.

### **Conclusion**

No claims are allowed.


**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Myron G. Hill  
Patent Examiner  
July 24, 2003

  
JAMES HOUSEL 7/28/03  
SUPERVISORY PATENT EXAMINER  
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